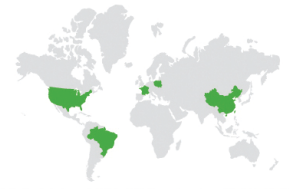




A WORLD OF MANUFACTURING EXPERTISE IN EVERY PART.



ISO 9001 AND ISO 13485 CERTIFIED

PRECISION-MACHINED COMPONENTS FOR MEDICAL APPLICATIONS

Case Studies



CASE STUDY: PROCESS IMPROVEMENT / COST REDUCTION / SPEED TO MARKET

Component: Phacoemulsification Handpiece

Challenge: Independently develop and share value-added process solutions with an established customer in order to obtain a better price position by improving the value stream.

Autocam Medical's Solution: In order to assist an established OEM customer with market pricing pressures, Autocam Medical's Process Improvement Team (PIT), comprised of engineering and manufacturing, proposed as solutions:

- Combine two-parts-into-one, which would eliminate electron beam weld of these two parts
- Eliminate one heat treat operation
- Eliminate a costly custom fabricated filler used in a laser weld process

Originally, this Surgical Handpiece design required machining of two pieces, a second process of electron beam welding which was followed by a heat treating process to complete this component before advancing to the assembly of a laser welded irrigation component. Autocam leveraged its expertise in machining and custom tool design and fabrication, which allowed the suggestion for a one-piece design and the elimination of the laser welding of the irrigation component in assembly. Autocam Medical worked concurrently with the customer's engineers to implement the improved design which benefited with lead times and allowed a 6% price reduction.

Benefit to the Customer: OEM could received their Surgical Handpieces with reduced overall lead times by several weeks with a 6% cost reduction allowing them to be more competitive in the marketplace.

Processes: CNC Lathe, Heat Treating, Laser Welding and Finishing Processes

CASE STUDY: RESPONSIVENESS / DESIGN FOR MANUFACTURABILITY / SPEED TO MARKET

Component: Implant Set

Challenge: A major Medical Orthopedic OEM requested a soft launch of 50 kits, including Implants: Plates, Screws, Buttons, Hooks and Instruments: Drivers, Drills, Depth Gauges and Guides – four months earlier than anticipated.

Autocam Medical's Solution: Because Autocam Medical was involved in the product's early planning, research and development stages, as well as provided prototypes and engineering support, the product was ready for launch earlier than expected. Based on positive testing results, the customer then decided on a soft launch to acquire valuable feedback from surgeons in the field. Committed to the success of the soft launch, Autocam Medical purchased additional technology, including state-of-the-art Matsuura CNC mills. Autocam Medical's thorough understanding of implant-to-instrument interface ensured a successful development process and an efficient design for manufacturability. Working overtime, Autocam Medical's team maximized their machining capacity to produce fifty complete kits with instruments and implants, in just four weeks.

Benefit to the Customer: Autocam Medical enabled their customer to launch a product line earlier than expected, allowing them to gain valuable user feedback from surgeons before committing to a final production run.

Processes: CNC Turned, CNC Milled, CNC Mill/Turn, Secondary Finishing, Subassembly

CASE STUDY: VALUE ENGINEERING / LEAD-TIME REDUCTION

Component: Surgical Drill

Challenge: Autocam Medical independently proposed changes in an existing drill design for an OEM in order to deliver cost savings without sacrificing performance.

Autocam Medical's Solution: Building on a history of manufacturing surgical drills for this customer, Autocam Medical's engineers proposed a two-piece laser-welded construction.

The following characteristics would remain consistent with the original design.

- Overall length and tolerance of overall length
- Flute geometry
- Laser marking
- All other geometry with the addition of a laser-weld location

The body of the drill would be made from 17-4 PH H-900 and the fluted portion would remain 455 SSH-900. These changes resulted in a more efficient production process and a 15% cost savings due to raw material selection, all without sacrificing performance of the existing cutting edge. Upon approval, this design change had a secondary benefit of lead-time reduction.

Benefit to the Customer: The OEM trimmed 15% off production costs without sacrificing quality or functionality of the drill.

Processes: CNC Turning, Secondary Finishing

CASE STUDY: RESPONSIVENESS / SPEED TO MARKET / PROTOTYPE TO HIGH-VOLUME PRODUCTION

Component: Micro-machined Vascular Surgical Component

Challenge: The customer needed a proof-of-concept and validation parts on a newly designed component, a barbed pusher body, for their vascular-closure device. The part was less than .170" in length with a maximum diameter of Ø.083" stepping down to Ø.042" where the barbs are located, and had a Ø.021" center thru-hole. Weekly volume requirements were up to 7,500 parts.

Autocam Medical's Solution: Purchased first CNC Swiss lathe, and in less than two weeks from delivery, Autocam Medical produced and delivered 200 First Article parts to the customer. Delivery of production parts began six days after delivery of First Article parts, with a total of 3,000 parts delivered in the first nine days. A second CNC Swiss lathe was delivered to Autocam Medical, with First Article parts from it produced in 3 days of machine receipt. Within first 10 months from program initiation Autocam Medical produced and delivered to the customer over 333,500 parts. This monthly average of 33,350 parts delivered, exceeded the customers minimum needs of 7,500 pieces delivered per week.

Benefit to the Customer: Autocam Medical completed prototype-to-high-volume production of a complex tight-toleranced part in less than six weeks from order placement. This allowed the customer to implement a quick product launch for their second generation vessel closure device.

Processes: CNC Swiss Lathe

CASE STUDY: PROBLEM SOLVING / SPEED TO MARKET

Component: Surgical Flex Drill

Challenge: The Medical Device OEM was receiving surgeon complaints about unsuccessful hip surgeries due to dull flex drills; these complaints were jeopardizing the customer's business. Autocam Medical was brought in to address the drill performance issues and develop a high-quality, quick-turnaround solution.

Autocam Medical's Solution: The customer received physician feedback that their original flex drills were so dull, they would bind or break during surgery. Because of Autocam Medical's earlier work with the customer's R&D group on a different drill design, the OEM asked Autocam Medical to take a look at this new problem. Autocam Medical listened carefully to the customer's request and used an "all hands on deck" approach to identify the critical issues and provide a new solution. In only seven days, they developed, manufactured and delivered 50 improved drills – enough to satisfy the surgeons' requirements and restore the business relationship. The Autocam Medical Quality team measured the new parts at 100% function, the parts were geometrically correct and the customer was extremely satisfied with the speed and accuracy of the parts. This positive feedback resulted in an extended production run.

Benefit to the Customer: Autocam Medical addressed the critical issues, and provided solutions to quickly repair the OEM's business relationship with its physicians.

Processes: CNC Turning, CNC Milling, CNC Grinding, Secondary Finishing, Subassembly

CASE STUDY: SPEED TO MARKET / PROTOTYPE TO HIGH-VOLUME PRODUCTION

Component: Precision-machined Vascular Component

Challenge: A leading Cardiovascular OEM called in Autocam Medical to address quality problems they were incurring with a component from another outsource vendor. This quality problem was negatively effecting their delivery requirements.

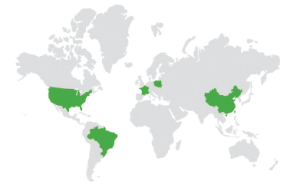
Autocam Medical's Solution: Autocam Medical was asked to use their expertise in manufacturability and capabilities to deliver the required quality component that could be produced in high volumes, with a "quick" start-of-production from approval of First Article validation parts. The First Article validation parts, 250 pieces, were sent on July 1. In less than two weeks from First Article validation parts being approved over 9,000 production parts were sent, followed by another 11,000 pieces in six business days, and over 63,000 pieces the following month. Autocam Medical's ability to ship in excess of 15,000 pieces per week for the following year exceeded the customers' expectations and needs, and all with zero defects.

Benefit to the Customer: Autocam Medical's capabilities benefited the customer by providing an alternative supplier who could provide high-quality product with fast start-up, and capacity that exceeded customers' needs.

Processes: SAS-16 Multi-spindle Screw Machine



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